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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	PAPER NUMBER
3766	
MAIL DATE	DELIVERY MODE
12/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,431	SANDERS, RICHARD S.	
	Examiner	Art Unit	
	DEBORAH MALAMUD	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 63-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 63-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 December 2008 has been entered.

2. Claims 8-62 are cancelled; new claims 63-75 are added; claims 1-7 and 63-75 are pending.

Response to Arguments

3. Applicant's arguments, see "Remarks," filed 10 December 2008, with respect to the rejection(s) of claim(s) 1-7 under Hafelfinger et al (U.S. 5,003,975) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Adams et al (U.S. 5,441,518).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 and 63-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 1 contains subject matter which was not described in the specification, specifically the use of extra-thoracic electrodes. The use of intrathoracic and transthoracic electrodes, including intracardiac and subcutaneous electrodes, is described in the Figures and disclosure, but no mention of extra-thoracic electrodes is provided. Methods are not provided for using extra-thoracic treatment of cardiac arrhythmias, and a structural relationship between the subcutaneous electrodes, intracardiac electrodes, implantable pulse generator and the extra-thoracic electrodes is not provided. Furthermore, the specification is simply void of any working examples or any description of how one of ordinary skill in the art would construct a system, or would use the system as claimed, to arrive at a configuration of electrodes that includes extra-thoracic electrodes.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3, 5-7 and 63-74 are rejected under 35 U.S.C. 103(a) as being anticipated by Hafelfinger et al (U.S. 5,003,975) in view of Adams et al (U.S. 5,441,518). Regarding claims 1, 63 and 65-73, Hafelfinger discloses (col. 4, lines 1-41; Figs. 1, 1a) "an implantable pacemaker that has electrode configuration programming capabilities, as well as, unipolar/bipolar lead interchangeability (meaning that either unipolar or bipolar operation may be programmed, and either unipolar or bipolar leads may be inserted into the pacemaker connector block). The present invention utilizes load recognition (i.e., the load impedance presented by the lead/tissue interface during a stimulation pulse) to determine the integrity of the implanted leads and to automatically change the electrode configuration to an available and operative configuration." The examiner considers this to be an implantable housing; a first electrode coupled to the housing and a second electrode; monitoring circuitry coupled to the first and second electrodes; and energy delivery circuitry coupled to the first and second electrodes. The device includes a "special monitoring circuit within the pacemaker that performs a lead impedance measurement whenever the operating configuration of the pacemaker is programmably changed, e.g., from bipolar to unipolar or vice versa. From this measurement, a determination is made as to whether the correct impedance is present for the existing operating configuration. If the expected impedance is not measured, then a different configuration measurement is made according to a predefined sequence until a correct impedance value is measured. The occurrence of a correct measurement is then used to set the pacemaker configuration accordingly." In other words, if a unipolar lead is sensed as connected to the device, the device is

programmed to disable the energy delivery circuitry used in a bipolar lead. Therefore, the examiner considers Hafelfinger to disclose a lead interface coupled to the housing; and a controller coupled to the lead interface, monitoring circuitry, and energy delivery circuitry, the controller transitioning operation of the device from the monitoring mode, in which the energy delivery circuitry (used for a bipolar lead) is disabled, to the energy delivery mode, in which the energy delivery mode, in which the energy delivery circuitry is enabled, at least in part in response to coupling the cardiac lead to the lead interface (since coupling the lead triggers the lead impedance sensing that determines the mode to be used by the device).

8. Hafelfinger discloses the claimed invention except for the use of subcutaneous electrodes. Adams however discloses, (col. 5, lines 36-45) "Pulse generator can (11) is implanted subcutaneously in conjunction with at least one other electrode, for example subcutaneous patch electrode (14). Pulse generator can is generally placed inferior to right or left subclavicular veins (16 or 18) for ease in vascular access. Subcutaneous patch electrode is placed anterolateral to the left lung (20) and chest wall (22). Heart electrodes such as right atrial (24), right ventricular (26) and pacing/sensing electrodes (28) are carried on catheters passed from pulse generator can to the heart (30) via venous access." Pulse generator can 11 (col. 5, lines 17-22) "contains within its housing a source for generating an electrical charge schematically represented by transformer (15), diode (17) and capacitor (19); independently programmable switch control circuit (13); switch circuit (21); and has its surface acting as pulse generator can electrode (12)." Adams further discloses (col. 6, lines 42-67; col. 7, lines 53-65)

switches (31, 32, 35 and 36) controlled by the programmable switch control (13) for creating mono- and bi-phasic countershock pulses dependent on sensed information. For instance, "If atrial fibrillation is detected either in conjunction with ventricular fibrillation or arising de novo as an isolated event, the choices for switch control are similar. For isolated atrial fibrillation, and by referring to FIGS. 3a and 3b, a preferred initial configuration would have right atrial electrode act as cathode in conjunction with pulse generator can electrode and/or subcutaneous patch electrode as anodes. A countershock of a much lower amplitude is then delivered to the atria, depicted by small closed arrows. Alternatively, the system could provide for concomitant pacing of the ventricles and timing the atrial countershock with the ventricular pacing." Adams discloses (col. 6, lines 55-59) "If this initial countershock is unsuccessful, one programmed response would be to reverse the polarity, thereby the ventricular apex electrode initially starts out as an anode with switches (31 and 36)." Adams and Hafelfinger both disclose systems and methods for stimulating a patient's heart using implanted electrodes. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hafelfinger's system for mode switching in response to coupling of a cardiac lead with Adams' subcutaneous electrodes in order to provide electrode configuration options that are minimally invasive with respect to the cardiac tissue, to reduce wear on a patient's heart.

9. Furthermore, Hafelfinger and Adams disclose the claimed invention but do not disclose expressly the use of only subcutaneous electrodes in one mode of operation. It would have been an obvious matter of design choice to a person of ordinary skill in

the art to modify the electrode configurations as taught by Hafelfinger and Adams, with the mode utilizing only subcutaneous electrodes, because the applicant has not disclosed the use of only subcutaneous electrodes provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the various electrode configurations as taught by Adams, because Adams' system is able to tailor a therapeutic strategy to a patient's needs as determined by collected sensed data. Therefore, it would have been an obvious matter of design choice to modify Adams' electrode configurations to obtain the invention as specified in the claims.

10. Regarding claim 2, Hafelfinger discloses (col. 7, lines 18-22; Fig. 2) a "sensing detector (60) is coupled to the terminal (46) to respond to sensed heart activity." The examiner considers this to be detection circuitry provided in the housing and coupled to the first and second electrodes.

11. Regarding claims 3 and 6, and further regarding claims 68 and 72, Adams discloses (col. 8, lines 28-35) the use of RAM-ROM (62) memory "for storing command functions, algorithms and data collected by system (10) designated to be downloaded via an external communications link."

12. Regarding claims 5 and 7, Hafelfinger discloses, (col. 7, lines 46-52; Fig. 3) "A configuration switch 80 is shown connected between pairs of leads (12 and 14) via connectors (82A, 82B) and the pacing stimulation and sense stage (40B). Also shown is the connection to the case (31). In conventional fashion, a control microprocessor

(84) or equivalent, is coupled to control the pacer stimulation and sense stage and the configuration switch." The examiner considers this to be a mode switch coupled to the controller; and a receiver coupled to the controller.

13. Regarding claim 64, the Examiner considers the lead electrodes of Adams and Hafelfinger to naturally be electrically and physically detachable with respect to the housing. Leads can always be removed from implantable devices with minimal or no damage to the system as a whole.

14. Regarding claim 74, Adams discloses (Abstract) the use of cardioversion and/or defibrillation therapy.

15. Claims 4 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafelfinger et al (U.S. 5,003,975) in view of Adams et al (U.S. 5,441,518) and in further view of Ideker et al (U.S. 6,205,357). Hafelfinger and Adams disclose the claimed invention except for a programmable filter coupled to the detection circuitry. Ideker however discloses (col. 7, lines 14-20) "electrodes shown in the positions illustrated panel 3A are, as shown in panel 3B, operatively connected to differential amplifiers (42, 42a, 42b, 42c), in turn connected to bandpass filters (44, 44a, 44b, 44c) and sensed event detector circuitry (46, 46a, 46b, 46c), contained in the ICD (40). Amplification and bandpass filtering are followed by sensed event detection." Hafelfinger and Ideker both disclose devices for switching between sensing and stimulating modes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hafelfinger's mode-switching and therapy-disabling system with Adams'

subcutaneous electrodes and with Ideker's programmable filter in order to eliminate any noise from the sensed signal and prevent a misdiagnosis.

16. Regarding claim 75, Ideker discloses (col. 15, lines 41-64) the use of resynchronization therapy when necessary for the patient.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH MALAMUD whose telephone number is (571)272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/
Examiner, Art Unit 3766